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10/528,829

03/23/2005

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/528,829 | <b>Applicant(s)</b><br>LEWIS ET AL. |  |
|                              | <b>Examiner</b><br>PAUL DICKINSON    | <b>Art Unit</b><br>1618             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 34-78 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 34-50 and 54-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-53 and 70-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group II (Claims 51-53) in the reply filed on 4/16/2008 is acknowledged. Applicant's election of the following in the same reply is also acknowledged: the composition of Claim 37 in which Y is  $\text{H}_2\text{C}=\text{C}(\text{CH}_3)\text{-CO-O}$ ; B is  $\text{CH}_2\text{-CH}_2$  and X is a compound of general formula III in which m is 2 and each  $\text{R}_5$  is  $\text{CH}_3$ .

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Claim 72 depends from Claim 35. The term "zwitterionic group" in Claim 35 is used by the claim to mean "ammonium" or "phosphonium", while the accepted meaning is "a group bearing both a positive and a negative charge." Ammonium and

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phosphonium each bear one negative and no positive charge. The term is indefinite because the specification does not clearly redefine the term.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 51 is rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 6416740 ('740). '740 discloses the administration of a composition to an animal, wherein the composition comprises particles of a polymer matrix into which is absorbed aqueous liquid, the particles having diameters in the range of 100 microns to 1 mm (1000 microns), wherein the surface of the particles express zwitterionic lipids (see abstract; col 4, lines 22-31; col 6, lines 5-8; col 20, line 46; Figures 1-3; Claim 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51 and 70-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11-322948 (JP '948; A machine translation of this document is provided and will be referenced to hereafter). JP '948 discloses a therapeutic composition comprising particles of a polymer matrix into which is adsorbed aqueous liquid, the particles having diameters in the range of 1 nm to 100,000 nm (100 microns) (see abstract; ¶ 4-17, 27-29; Claims 1-3). The spherical particles comprise a copolymer of 2-(methacryloyloxy) ethyl 2-(trimethylammonio) ethyl phosphate and n-butyl methacrylate, wherein the

zwitterionic 2-(trimethylammonio) ethyl phosphate is expressed on the surface (see ¶ 27-29). JP '948 teaches the utility of the composition as a drug delivery system for therapeutic treatment (see ¶ 1-3).

JP '948 fails to disclose the diameter range 40 to 4000 microns. JP '948 further fails to explicitly teach administration of the composition to an animal for therapy or diagnosis.

It would be obvious to one of ordinary skill in the art at the time the invention was made to administer the composition disclosed by JP '948 to an animal for therapeutic treatment, with a reasonable expectation of success, as JP '948 teaches the utility of the composition as a drug delivery system for therapeutic treatment. It would be further obvious to find the instantly disclosed diameter range of 40 to 4000 microns through routine experimentation, as the diameter range disclosed by JP '948 of 1 nm to 100 microns overlaps with this range, to produce more effective drug delivery systems. See MPEP § 2144.05, II.

Instant Claim 76 depends from Instant Claim 47 and the latter claim is directed to the properties of the composition when imbued with physiological saline at room temperature. Instant Claim 78 depends from Instant Claim 49 and the latter claim is directed to the properties of the composition when imbued with water. Although JP '948 does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the composition disclosed by

JP '948. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).” MPEP 2112, I.

Claims 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11-322948 (JP '948) in view of WO 0103666 (WO '666) in further view of Ishihara et al (Ishihara et al, Molecular design and preparation of bioinspired phospholipid polymer as novel biomaterials, *Polymer Preprints*, 2001, 42(2), 117-118). The relevant portions of JP '948 are provided above in the rejection of Claims 51 and 70-78 under 35 U.S.C. 103(a). JP '948 fails to teach administering the composition to an animal to form an embolus.

WO '666 teaches that polymeric materials comprising phosphoryl choline (2-(trimethylammonio) ethyl phosphate) serve as effective embolization materials (see abstract; page 1, lines 6-14; page 6, lines 1-17; Claim 17).

Ishihara et al teach the excellent biocompatible and antithrombogenic properties of acrylate copolymers of 2-methacryloyloxyethyl phosphorylcholine (2-

(methacryloyloxy) ethyl 2-(trimethylammonio) ethyl phosphate) and their administration to the arteries of a patient (see Experimental Section; Conclusion).

It would be obvious to one of ordinary skill in the art at the time the invention was made to administer the composition disclosed by JP '948 to the arteries of an animal, with a reasonable expectation of success, to form an embolus, as WO '666 teaches the effectiveness of phosphorylcholine polymers as embolization materials and Ishihara et al teaches the biocompatible and antithrombogenic properties of such compositions.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

May 19, 2008